UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,240	04/08/2004	Nisar Ahmed Khan	3077-6384US	9732

24247 7590 01/09/2007

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,240	KHAN ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *1-26 and 31-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :040408; 040517; 051007; 051220; 060412; 061217.

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Karlheinz R. Skowronek whose telephone number is (571) 272-9047.

Election/Restrictions

Applicant's election without traverse of group III (claims 27-30) in the reply filed on 17 October 2006 is acknowledged.

Claim Status

Claims 1-46 are pending.

Claims 1-26 and 31-46 are withdrawn from examination as being drawn to a non-elected group.

Claims 27-30 are being examined.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/753,510, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 10/753,510 does not a method of producing a pharmaceutical comprising the establishment of a distribution system and a sales group for marketing the pharmaceutical. Accordingly, claims 27-30 are not entitled to the benefit of the prior application.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 4/8/04,5/17/04,10/7/05,12/20/05, 4/12/06, and 12/7/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Specification

The use of the trademark BAYTRIL (Bayer), RNEASY(Qiagen) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "Accentuation" in claim 27 is a relative term which renders the claim indefinite. The term "Accentuation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear from the claim what is being “accentuated”, sepsis or the protection from sepsis. Appropriate correction is requested. Claims 28-30 are also rejected because they depend from claim 27, and thus contain the above issues due to said dependence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al (US Pg pub 2002/017306).

The claims are directed to a method of producing a pharmaceutical compound by identifying a compound that modulates immune reaction by searching a peptide database, conducting a therapeutic profiling of the compound for efficacy and toxicity, formulating a pharmaceutical preparation, establishing a distribution system for distributing the pharmaceutical, and establishing a sales group to market the pharmaceutical.

Lin et al teach a method of producing a pharmaceutical in which the identity of a compound is determined which modulates glucose tolerance. It is generally accepted in the art that individuals that have diabetes have an altered tolerance to glucose levels and therefore a compound as disclosed in Lin et al to modulate or provide a therapeutic benefit for diabetes would modulate glucose tolerance. In Lin et al, compounds are identified that modulate the signaling pathways that include ephrin-PDZ interactions (p. 2, [0020]) that provide a therapeutic benefit to diseases of the immune system (p. 3, [0033]). One disclosed assay system is a search of members of a random peptide library reading on searching a peptide database (p. 15, [0158]). The identified compounds are profiled therapeutically for efficacy toxicity and in animals (p. 2, [0021]). Suitable compounds are then formulated into a pharmaceutical preparation (p. 2, [0022]). Lin et al disclose further that method also includes the steps of establishing a sales group for marketing the pharmaceutical and establishing a distribution system for distributing the pharmaceutical preparation (p. 2, [0023]).

Claims 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorczynski et al (US Pg pub 2005/0107314).

The claims are directed to a method of producing a pharmaceutical compound by identifying a compound that modulates immune reaction by searching a peptide database, conducting a therapeutic profiling of the compound for efficacy and toxicity, formulating a pharmaceutical preparation, establishing a distribution system for distributing the pharmaceutical, and establishing a sales group to market the pharmaceutical.

Gorczynski et al teach a method of producing a pharmaceutical in which the identity of a compound is determined which modulates immune response reading on systemic inflammatory reponse. In Gorczynski et al, compounds are identified that modulate the signaling pathways that include CD200 receptor (p. 14, [0196]) that provide a therapeutic benefit to diseases of the immune system (p. 16, [0226]). The identified compounds are profiled therapeutically for efficacy toxicity and in animals (p. 14, [0197]). Suitable compounds are then formulated into a pharmaceutical preparation (p. 14, [0198]). Gorczynski et al disclose further that method also includes the steps of establishing a sales group for marketing the pharmaceutical and establishing a distribution system for distributing the pharmaceutical preparation (p. 14, [0199]).

Conclusion

No claims allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/
KRS

MICHAEL BORIN, PH.D
PRIMARY EXAMINER